TGN 37 Guidance for a Risk Assessment under Annex III of Directive 2014/30/EU

Guidance for a Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/30/EU[01] (The EMC Directive).

1. The Issue:

Under Directive 2014/30/EU, Annex III, Part A, Module B 3(c) (The EMC Directive), it is required that a Notified Body shall assess the technical documentation associated with the apparatus to ensure conformity with the applicable requirements of the Directive and that the technical documentation shall include an adequate analysis and assessment of the risk(s).

Risk assessment is an activity for the manufacturer alone to perform but the Notified Body shall take the manufacturer's risk assessment into account as provided in the manufacturer's technical documentation, when performing an EU-Type Examination assessment under Annex III of the EMC Directive. The purpose of this document is intended to provide guidance to Notified Bodies as to the recommended issues that can be expected to be considered in a risk assessment document and to achieve a consistent approach between various Notified Bodies such that manufacturers are not burdened by unnecessary differences and expectations from different Notified Bodies. This document is not intended to be guidance to manufacturers nor is it intended to influence market surveillance authorities. Furthermore, it is not applicable to professional devices covered by Directive 2013/35/EU.

2. Risk analysis and assessment submitted by manufacturer

The risk analysis presented by the manufacturer and assessed by the Notified Body shall follow the guidance given in 'Blue Guide' on the implementation of EU product rules 2016"[02] under clause 4.3 and clause 4.1.2.2.
The figure given in 4.1.2.2 of the "Blue Guide" can be used as guidance:

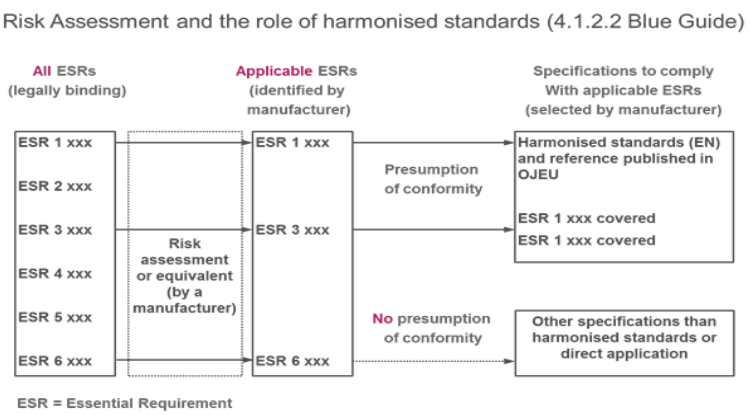

Figure 1 Guidance on how to assess the ESR required taken from Blue Guide [01] clause 4.1.2.2

The risk analysis and assessment shall consider and document at least the following steps:

1. Clearly identifying the intended user groups (e.g. professional, consumer, children etc.), the operating environment (e.g. Indoor/outdoor, temperature, altitude, etc.) and the operating modes for which the product is intended to be used.
2. Identifying which of the Essential Requirement(s) of the directive are applicable.
3. Identifying which harmonized standard(s) or equivalent documentation has been applied to mitigate the risk of non-compliance to the Essential Requirements.
4. Specifically identifying if there are special product characteristics or features which might be not included in the current harmonised standard(s) so far (e.g. because it is a new invention) then the risk regarding the essential requirements should be dealt and how these features are still considered to comply with the Essential Requirements.
5. Specifically explaining how the additional risks in not following the available harmonised standards giving a presumption of conformity or not using alternative compliance methods and standards have been mitigated to demonstrate compliance to the Essential Requirements (for example if any port or any operating mode has not been tested, worst case explanation, etc.).

3. Tasks of the Notified Body

The Notified Body shall check whether the risk analysis presented is compliant with the minimum requirements in the Blue Guide and take into consideration the content of this guide. The notified body shall take into account for their assessment the information presented in the risk analysis and assessment by the manufacturer.

The notified body shall allow any format and structure of the risk analysis and assessment as part of the technical documentation because this can only be entirely determined by the manufacturer. The risk assessment shall however be in a language that can be understood by the Notified Body.

The Notified Body shall consider if the manufacturer's defined user groups and operational conditions are appropriate. Is the product intended to be used by vulnerable people? Is the product intended to be used in conditions outside of the scope of the applied harmonised standards?

The Notified Body shall assess if the harmonised standards, other normative documents and reference documents applied by the manufacturer entirely cover the essential requirements for which they have been selected.

If the product is covered by more than the EMCD, then a more onerous risk assessment may be required by the other directive. The EMCD NB should take care not to exceed their remit under the EMCD unless agreed by the manufacturer and they are competent to do so.

The Notified Body shall take care that any exceptional product characteristics identified are considered in the risk assessment which might not have been dealt with or known at the time the applied harmonised standard(s) had been prepared. It can be expected that this may only occur in very rare, exceptional cases. The type of questions a Notified Body could ask when asked to review the technical documentation are related mainly to the Essential Requirements of Annex 1 of the Electromagnetic Compatibility Directive they have been asked to assess.

For Electromagnetic Compatibility a Notified Body may wish to consider the following aspects during an assessment of the technical documentation to ensure that the product has been appropriately evaluated for both emissions and immunity characteristics.

Emissions:

a. What frequency range has the product been tested over? Consider the range of clock frequencies used within the product.
b. Are the technologies within the product likely to cause EM disturbances below the lowest frequency of test on the power cable?
c. If the product has 'other' ports (i.e. other than power), have they been tested? If not, are they likely to cause radiated disturbances due to their length? How has the manufacturer mitigated this?
d. Does the product have telecom cables? Has testing been performed on these ports? If not, why? Is the mitigation reasonable under foreseeable circumstances?
e. Are the technologies within the product likely to cause EM disturbances above the highest frequency of test? Consider the operating frequencies of the product and what communication services should be protected (note many product standards now require testing to 6 GHz due to the multitude of radio services in the 1-6 GHz bands).
f. Are there any other unique factors within the product that should be considered (i.e. intentional radiators, but not radio communications)?

Immunity:

a. Have tests been performed that cover all the phenomena covered by the generic standards?
b. Are the immunity levels appropriate for the EM environment? Are there ports on the product which are liable to be susceptible and haven't been tested?
c. Have Common Mode transients and appropriate RF immunity tests been evaluated?
d. Have Transients and surges been evaluated if use in a vehicular environment is specified?
e. If no harmonised standard has been applied: Check if all relevant phenomena as listed in the generic immunity standard have been considered in the evaluation and in tests done. Also annex 3 of Guide for the EMCD (Directive 2014/30/EU) can be considered.

4. Conclusion:

It is recommended that NBs assure themselves that the manufacturer's risk assessment does reach a conclusion that the product satisfies the Essential Requirements as applicable to the product. This may be clarified or illustrated by the manufacturer with statements as to the state-of-the-art knowledge and reasonably foreseen, legal use of the equipment as required by the manufacturer. The conclusion of the risk assessment is separate to the manufacturer's EU Declaration of Conformity.

Disclaimer: "Manufacturers have to carry out a risk analysis to first identify all possible risks that the product may pose and determine the essential requirements applicable to the product. This TGN is limited to the essential requirements of the Electromagnetic Compatibility Directive 2014/30/EU (EMCD). The manufacturer is responsible to cover all requirements of all legislative acts applicable to a given product or whether the product in question introduces also other risks not considered by the EMCD."

References:

[01] DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

[02] COMMISSION NOTICE of 5.4.2016 The 'Blue Guide' on the implementation of EU product rules 2016; Brussels, 5.4.2016 C(2016) 1958 final.

[03] Guide for the EMCD (Directive 2014/30/EU)

Annex (Informative)

This annex is intended to give some useful guidance to a Notified Body if they are reviewing a risk assessment where the manufacturer has not applied harmonised standards or if the product characteristics require an evaluation beyond the scope of the harmonised standards.

The aim of this TGN is not to set prescriptive limits but rather to indicate to Notified Bodies where useful information can be obtained which shows the current “State of The Art” for EMC performance above and below the frequencies defined in the current, commonly used EMC Generic Standards such that a practical consideration of the manufacturer’s mitigation techniques can be consistently evaluated.

When a Notified Body is performing an EU-type examination assessment, the NB should be aware of the current situation for EMC performance below 150 kHz and above 1GHz. For the protection of the radio spectrum below 150 kHz there are limits for conducted emission as well as radiated magnetic field emission available from CISPR standards which have been adopted by EU. Examples are: EN 55014-1, EN 55015 and EN 55011. For the protection of products connected by wires there is a standard available from IEC TC 77 for the frequency range from 2 kHz to 30 kHz (IEC 61000-2-2/AMD1 ED2). For the frequency range from 30 kHz to 150 kHz there is a draft presented
(77A/980/CDV.IS until 2019-04-30). Based on these compatibility limits for symmetrical signals on wires; CISPR has started work to derive limits for the protection of the radio spectrum within this frequency range which then might additionally be used for generic products beside the limits already available in EN 550141, EN 55015, EN 55011. Manufacturers may also consider the FCC 15.109 and 15.209 limits, which go down to 9 kHz. Additionally, ERC/REC 74-01 gives limits down to 9 kHz. So, this means the general limits which are valid for all kinds of equipment are not yet readily available.

Standards available under the EMC directive 2014/30/EU do have limits and test levels available above 1 GHz up to 6 GHz or 18 GHz (e.g. EN 55032, EN 55035, EN 55011, IEC 61000-6-X series). CISPR has decided in its plenary 2017 to start work on establishing general available test methods and limits for products from 6 GHz to 40 GHz. This is relevant for all products due to the universal presence of 5 GHz Wi-Fi apparatus being commonly encountered in all operating environments.

Disclaimer
This EUANB Technical Guidance Note does not replace the text of the EMCD – 2014/30/EU - is for guidance only. In legal disputes the text of the EMCD, or its implementation in National legislation takes precedence.

***** End of TGN **********